K113744
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Section 5 – 510(k) Summary

Date Prepared:	January 31, 2011
Company:	Angiotech 100 Dennis Dr. Reading, PA 19606
Contact:	Kirsten Stowell Regulatory Affairs Manager Phone: 610-404-3367 Fax: 610-404-3924 Email: kstowell@angio.com
Device trade name:	Quill™ PDO Knotless Tissue-Closure Device (Polydioxanone)
Device Common Name:	Polydioxanone Absorbable Surgical Suture
Device classification:	Absorbable Polydioxanone Surgical Suture Product code, NEW 21 CFR 878.4840 Class II
Legally marketed devices to which the device is substantially equivalent:	K051609: Quill Synthetic Absorbable Barbed Suture K082662: V-Loc 180 Absorbable Wound Closure Device
Description of the device:	The Quill™ Knotless Tissue-Closure Device comprised of PDO (Polydioxanone) is a synthetic absorbable tissue-closure device that is intended for use in the closure of soft tissue. It is comprised of polyester [poly (p-dioxanone)] monofilament suture material, dyed with D&C Violet No. 2. The device is designed with small uni-directional barbs along the length of the device, and a welded loop at the distal end which is used to form the secondary variable loop, used to secure the device at the distal end. The device is available in diameter Size 0 in various lengths affixed to various needle types.
Indications for Use:	Quill™ PDO Knotless Tissue-Closure Device, comprised of Polydioxanone, is indicated for soft tissue approximation where use of an absorbable suture is appropriate.

Substantial Equivalence:

The Quill™ Knotless Tissue-Closure Device comprised of PDO (Polydioxanone) has the same design and materials as its predicates, including the same intended use, technological characteristics and size ranges as the predicate devices.

The intended use is identical to both predicate devices. The material and chemical composition of the proposed device is identical to the predicate Quill Synthetic Absorbable Barbed Suture (K051609). The design of the proposed device is similar to the predicate V-Loc 180 Absorbable Wound Closure Device regarding the uni-directional barbs and the welded loop on the distal end. The technique used for deployment of the device is similar to the predicate V-Loc 180 Absorbable Wound Closure Device (K082662).

Performance tests:

Non-clinical laboratory performance testing was conducted to confirm that the Quill™ Knotless Tissue-Closure Device comprised of PDO (Polydioxanone) conforms to the USP monograph for absorbable sutures for tensile strength (as applicable) and needle attachment. This testing was performed in accordance with FDA's Class II Special Controls Guidance Document: Surgical Sutures, Issued June 3, 2003.

The results of this testing demonstrates that the Quill™ Knotless Tissue-Closure Device comprised of PDO (Polydioxanone) is substantially equivalent in safety and performance to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 1 2012

Angiotech
% Ms. Kirsten Stowell
100 Dennis Drive
Reading, Pennsylvania 19606

Re: K113744
Trade/Device Name: Quill PDO Knotless Tissue-Closure Device (Polydioxanone)
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW
Dated: December 19, 2011
Received: January 09, 2012

Dear Ms. Stowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

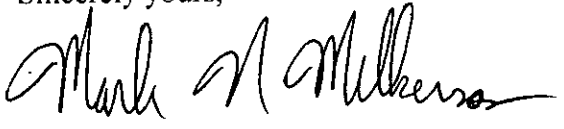
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

510k number if known: _____

Device Name: Quill™ PDO Knotless Tissue-Closure Device, Polydioxanone

Indications for Use:

Quill™ PDO Knotless Tissue-Closure Device, comprised of Polydioxanone, is indicated for soft tissue approximation where use of an absorbable suture is appropriate.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113744